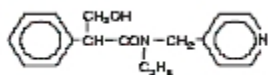


TROPICAMIDE - tropicamide solution/ drops

Bausch & Lomb Incorporated

DESCRIPTION

Tropicamide Ophthalmic Solution, is an anticholinergic prepared as a sterile topical ophthalmic solution in two strengths. The active ingredient is represented by the following structural formula:



$C_{17}H_{20}N_2O_2$ Mol.wt. 284.36

Benzeneacetamide, *N*-ethyl- α -[hydroxymethyl]-*N*-[4-pyridinylmethyl]-

Each mL Contains:

Tropicamide Ophthalmic Solution USP, 1% ACTIVE: Tropicamide, 10 mg (1%); INACTIVES: Boric Acid, Hydrochloric Acid, Edetate Disodium, Purified Water. Sodium Hydroxide and/or Hydrochloric Acid may be added to adjust pH (4.0 - 5.8).

PRESERVATIVE ADDED: Benzalkonium Chloride 0.01%.

Tropicamide Ophthalmic Solution USP, 0.5% ACTIVE: Tropicamide, 5 mg (0.5%); INACTIVES: Boric Acid, Edetate Disodium, Hydrochloric Acid, Purified Water. Sodium Hydroxide and/or Hydrochloric Acid may be added to adjust pH (4.0 - 5.8).

PRESERVATIVE ADDED: Benzalkonium Chloride 0.01%.

CLINICAL PHARMACOLOGY

This anticholinergic preparation blocks the responses of the sphincter muscle of the iris and the ciliary muscle to cholinergic stimulation, dilating the pupil [mydriasis]. The stronger preparation (1%) also paralyzes accommodation. This preparation acts rapidly and the duration of activity is relatively short. The weaker strength (0.5%) may be useful in producing mydriasis with only slight cycloplegia.

INDICATIONS AND USAGE

For mydriasis and cycloplegia for diagnostic procedures.

CONTRAINDICATIONS

This product is contraindicated in persons with primary glaucoma or a tendency toward glaucoma (e.g. narrow anterior chamber angle), and in persons showing hypersensitivity to any component of this preparation.

WARNINGS

For topical use only - not for injection. Reproductive studies have not been performed in animals.

There is no adequate information on whether this drug may affect fertility in human males or females or have a teratogenic potential or other adverse effect on the fetus. This preparation may cause CNS disturbances which may be dangerous in pediatric patients. Possibility of occurrence of psychotic reaction and behavioral disturbance due to hypersensitivity to anticholinergic drugs should be borne in mind.

PRECAUTIONS

General

In the elderly and others where increased intraocular pressure may be encountered, mydriatics and cycloplegics should be used cautiously. To avoid inducing angle closure glaucoma, an estimation of the depth of the angle of the anterior chamber should be made. The lacrimal sac should be compressed by digital pressure for two to three minutes after instillation to avoid excessive systemic absorption.

Information for patients

Do not touch dropper tip to any surface as this may contaminate the solution. Patients should be advised not to drive or engage in other hazardous activities while pupils are dilated. Patients may experience sensitivity to light and should protect eyes in bright illumination during dilation.

Parents should be warned not to get this preparation in their child's mouth and wash their own hands and the child's hands following administration.

ADVERSE REACTIONS

Increased intraocular pressure. Psychotic reactions, behavioral disturbances, and cardiorespiratory collapse in pediatric patients and some adults with this class of drugs have been reported.

Transient stinging, dryness of the mouth, blurred vision, photophobia with or without corneal staining, tachycardia, headache, parasympathetic stimulation, or allergic reaction may occur.

DOSAGE AND ADMINISTRATION

For refraction, one or two drops of the 1% solution in the eye(s), repeated in five minutes. If patient is not seen within 20 to 30 minutes, an additional drop may be instilled to prolong mydriatic effect. For examination of fundus, one or two drops of the 0.5% solution 15 or 20 minutes prior to examination.

Individuals with heavily pigmented irides may require larger doses.

HOW SUPPLIED

Tropicamide Ophthalmic Solution USP, 1% is supplied in a plastic bottle with a controlled drop tip in the following sizes:

2 mL bottle - Prod. No. 07403

15 mL bottle - Prod. No. 07411

Tropicamide Ophthalmic Solution USP, 0.5% is supplied in a plastic bottle with a controlled drop tip in the following size:

15 mL bottle - Prod. No. 07311

STORAGE

Store between 15°-30°C (59°-86°F).

Do not refrigerate. Do not store at high temperatures. Keep container tightly closed.

DO NOT USE IF IMPRINTED "Protective Seal" WITH YELLOW IS NOT INTACT.

KEEP OUT OF REACH OF CHILDREN.

STERILE OPHTHALMIC SOLUTION

Rx only

MANUFACTURER INFORMATION

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